AMERICAN PHARMACEUTICAL PARTNERS, INC.

April 8, 2003

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 79N-0113

WITHDRAWAL OF HEARING REQUEST

Dear Sir or Madam:

Reference is made to the attached November 14, 1984 request for a hearing by Lyphomed, Inc. regarding the efficacy of their Multivitamin Concentrate product. This Grandfathered product was purchased by Fujisawa USA from Lyphomed in 1991. The product was in turn purchased by American Pharmaceutical Partners, Inc. (APP) from Fujisawa USA in June 1998. Since that time, APP has discontinued the manufacture and marketing of the Multivitamin Concentrate product. Therefore APP no longer desires to pursue the hearing request and hereby withdraws the request.

If you have any questions regarding this matter, please contact the undersigned at **(708) 486-2071.**

Sincerely,

Dale Carlson
Associate Director, Regulatory Affairs

79N-0113

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LyphoMed

ADMIN PROCEEDINGS STAFF

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November 14, 1984

Dockets Management Branch
(HFA-305) Room 4-62
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

To Whom It May Concern:

The published notice in the Federal Register of September 17, 1984 (49FR36446) has stated that the FDA has reviewed all available evidence regarding the efficacy of parenteral multivitamin drug products, and has concluded that certain formulations are deemed effective.

The notice also clarified other formulations as lacking substantial evidence of effectiveness and proposed withdrawal of conditional approval of new drug applications that provide these formulations.

Multi Vitamin Concentrate, marketed by LyphoMed, Inc., is similar to a drug product listed in the Federal Register as lacking evidence of efficacy. Enclosed in this correspondence is specific data in the form of clinical investigations, and review articles which we feel supports the position that our intravenous vitamin product is both safe and effective, and should not be withdrawn from the marketplace.

Therefore, in accordance with 21 CFR 314.200, LyphoMed, Inc. requests an opportunity for hearing regarding the issue of efficacy of our multivitamin concentrate product.

Sincerely,

D. P. Shah

Dilip P. Shah, Ph.D.
Vice President, Regulatory Affairs

DPS/sz

encl

LyphoMed, Inc.
2020 Ruby Street • Melrose Park, Illinois 60160
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